

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
WEST. DIV. CINCINNATI

UNITED STATES OF AMERICA,

CASE NO. 1-24-00000

Plaintiff,

JUDGE BARRETT

V.

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JAMES COHEN,

INFORMATION

Defendant.

21 U.S.C. § 331(a)

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THE UNITED STATES ATTORNEY CHARGES:

1. The Food and Drug Administration (“FDA”) was the agency of the United States responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”). Among the purposes of the FDCA was to ensure that devices sold for administration to humans, or for other use by or on humans, provide reasonable assurances of safety and effectiveness.
2. Under the FDCA, all contact lenses were deemed to be devices pursuant to 21 U.S.C. § 360j(n)(1).
3. Contact lenses were also prescription devices. A prescription device is a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device. 21 C.F.R. § 801.109.
4. It was unlawful to introduce or deliver for introduction into interstate commerce any device that was misbranded. 21 U.S.C.A. § 331(a).

5. A device was deemed to be misbranded if its labeling lacked adequate directions for use, unless the Secretary of Health and Human Services promulgated regulations exempting the device from this requirement pursuant to 21 U.S.C. § 352(f)(1).
6. “Adequate directions for use” was defined by regulation as “directions under which the layman can use the device safely and for the purposes for which it is intended.” 21 C.F.R. § 801.5. Because prescription devices by definition can only be used safely under the supervision of a licensed medical practitioner, there could be no adequate directions for laymen to use them, and such devices must qualify for an exemption to this requirement to move in interstate commerce. 21 C.F.R. § 801.109.
7. A prescription device that was distributed or dispensed without a prescription would be deemed to be misbranded because its labeling lacks adequate directions for lay use and it is not exempt from the adequate directions for use requirement. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 801.109.
8. Contact lenses had a potentiality for harmful effect, including scratches on the cornea, corneal infection, conjunctivitis, decreased vision, and blindness. Accordingly, the use of contact lenses was not safe “except under the supervision of a practitioner licensed by law to the direct the use of such device” and “adequate directions for use” could not be prepared pursuant to 21 C.F.R. § 801.109.

COUNT 1

**(Introduction of Misbranded Device into Interstate Commerce
With Intent to Defraud or Mislead)**

9. Paragraphs 1 through 8 of the Information are incorporated here.
10. From in or around June 2014 to in or around November 2019, in the Southern District of Ohio and elsewhere, the defendant, **JAMES COHEN**, with the intent to defraud and

mislead, introduced and delivered for introduction into interstate commerce a device that was misbranded, to wit, without requiring a prescription, the defendant, **JAMES COHEN**, sold, shipped, and caused to be shipped misbranded colored contact lenses from Orlando, Florida to the Southern District of Ohio while failing to provide adequate directions for use and after falsely advertising the colored contact lenses as FDA-approved, non-prescription contact lenses.

In violation of 21 U.S.C. §§ 331(a), 333(a)(2).

FORFEITURE ALLEGATION

Upon conviction of the offense set forth in Count 1 of this Information, the defendant, **JAMES COHEN**, shall forfeit to the United States, pursuant to 21 U.S.C. § 334(a)(2)(D) and 28 U.S.C. § 2461(c), any misbranded device in the form of a money judgment in the amount of \$50,625.23.

SUBSTITUTE ASSETS

If any of the property described above, as a result of any act or omission of the defendants:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p) as incorporated by 28 U.S.C. § 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property described above, including the following:

- Contents of Suntrust account number ending in 8918 in the business name of Funky Eyes International, Inc. and in the approximate amount of \$3,277.31 seized on or about November 14, 2019; and,
- Contents of Suntrust account number ending in 9312 in the business name of Funky Eyes International, Inc. and in the approximate amount of \$47,347.92, seized on or about November 14, 2019.

U.S. DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH

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Director



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